

Appl. No. 09/913,874  
Amdt. dated March 9, 2004  
Reply to Final Office Action of December 9, 2003

### REMARKS

Entry of the Amendments is respectfully requested. Applicants submit the Amendment places the application in condition for allowance and raises no issues not previously considered by the Examiner.

Claims 10-15 have been canceled. Claims 1 and 7 have been amended to further clarify the invention. Applicants submit the amendments are supported throughout the specification, including at page 2, lines 23-24, and page 13, lines 27-30, and do not raise any issues of new matter.

Applicants respectfully request claim 9 be rejoined. In view of the amendment to claim 1, Applicants submit claim 9 in its current form is limited to a kit comprising an allowable enzyme.

#### Allowable Subject Matter

The Examiner objected to claims 7 and 8 as being dependent upon a rejected base claim. The Examiner indicated claims 7 and 8 would be allowable if rewritten in independent form. Applicants amended the claims as suggested by the Examiner. Accordingly, withdrawal of the objection is respectfully requested.

#### Anticipation

1) The Examiner rejected claims 1 and 6 under 35 U.S.C. § 102(b) as anticipated by WO 98/48043. The Examiner alleges the proteases in Tables 1 and 2 anticipate Applicants' claimed enzyme. Applicants respectfully traverse this rejection.

The Examiner stated that although the activities of the proteases listed in Tables 1 and 2 are fairly non-specific, if given enough time a single glycosylated amino acid, such as a glycosylated valine if present, could reasonably be expected to be released from a glycosylated protein. Applicants respectfully disagree. Moreover, claim 1 is directed to an isolated enzyme that specifically releases an amino acid having a glycosylated  $\alpha$ -amino group from a glycosylated protein or a glycosylated peptide. WO 98/48043 does not teach that any of the proteases in Tables 1 and 2 specifically release a glycosylated  $\alpha$ -amino group, nor is such an activity required in the method described in the reference. Therefore, WO 98/48043 does not disclose every element of Applicants' claims.

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In view of the claim amendment and foregoing remarks, Applicants respectfully request withdrawal of this rejection.

2) The Examiner rejected claims 1 and 6 under 35 U.S.C. § 102(b) as anticipated by Shin et al. The Examiner asserts the protease disclosed by Shin et al., which is allegedly obtained from the same genus and species and shares the property of being able to hydrolyze proteins, demonstrates a reasonable probability that the protease is identical or sufficiently similar to Applicants' claimed enzymes such that whatever differences exist with the claimed enzymes are not patentably significant. Applicants respectfully traverse this rejection.

In order to rely on inherency the Examiner must provide a basis in fact and/or technical reasoning to reasonably support the determination that the allegedly inherent characteristic necessarily flows from the teachings of the applied prior art. *Ex parte Levy*, 17 USPQD2d 1461, 1464 (Bd. Pat. App. & Inter. 1990) (emphasis in original). Probabilities or possibilities are not sufficient to establish inherency. *In re Robertson*, 169 F.3d 743, 745 (Fed. Cir. 1999).

Applicants' claims are directed to an isolated enzyme derived from *Corynebacterium ureolyticum* KDK1002 (FERM P-17135) or *Pseudomonas alcaligenes* KDK1001 (FERM P-17133) wherein the enzyme specifically releases a glycosylated  $\alpha$ -amino group. Shin et al. do not appear teach an isolated alkaline protease. Shin et al. describe using fish meal wastewater as a carbon and nitrogen source for alkaline protease producing *Pseudomonas alcaligenes*. The reference describes the effect of nitrogen and carbon source on enzyme production (abstract and figures 2 and 3) of *P. alcaligenes* and an assay employing an enzyme solution from *P. alcaligenes* (figure 1) but does not appear to teach an isolated and/or purified enzyme having a specific activity, such as  $\alpha$ -glycosylated amino acid releasing activity.

Shin et al. describe a strain of *P. alcaligenes* cultured from sea water (abstract). Applicants, however, isolated the claimed enzyme from a strain of *P. alcaligenes* cultured from soil (specification at page 3, lines 36-37). Sea water and soil are very different environments for bacterial growth and survival. Given the physical and chemical differences in the environments from which the bacterial strains were isolated, a strain of *P. alcaligenes* cultured from sea water would not necessarily have the same biochemical characteristics as a strain of *P. alcaligenes* cultured from soil. For example, the strain of *P. alcaligenes* isolated by Applicants' (KDK1001) utilizes glucose as a carbon source (specification at page 4, line 30) whereas the strain of *P.*

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*alcaligenes* isolated by Shin et al. does not utilize glucose as a carbon source (page 140, table 3). In view of the chemical and physical differences in the environments from which the bacterial strains were isolated and the biochemical differences between the different bacterial strains, the property of hydrolyzing any protein (which forms the basis for the inherency rejection) does not demonstrate a reasonable probability that the protease allegedly disclosed by Shin et al. is identical or sufficiently similar to the claimed enzyme.

Applicants submit Shin et al. does not teach every element of the claim, either expressly or inherently. The Examiner has provided no basis in fact or technical reasoning supporting the determination that an enzyme with specific  $\alpha$ -glycated amino acid releasing activity necessarily flows the teachings of Shin et al. Withdrawal of the anticipation rejection is respectfully requested.

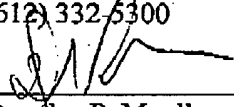
#### Conclusion

In view of the amendments and remarks presented herein, favorable reconsideration in the form of Notice of Allowance is respectfully requested. The Examiner is invited to telephone the undersigned for clarification of any of the amendments and remarks or to otherwise facilitate prosecution of the application.

Respectfully submitted,

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